INFORMED CONSENT IN PEDIATRIC PRACTICE: LEGAL AND ETHICAL ISSUES

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Abstract

In the medical practice, health professionals are legally obliged to obtain the informed consent from their patients before performing any invasive medical procedure. In the case of minors, society and law presume that children are not able to make major life decisions on their own, and the rules that exist to deny children the right to make decisions independently, generally serve to protect them (Koocher &Keith-Spiegel, 1990). Parents have legal authority to make all decisions on behalf of their children, including medical decisions. Parents are always two, as a rule. It means that not only one parent, but both of them need to agree to medical invasive treatments of their children. This paper will present the particularity of the informed consent in pediatrics according to the regulations on the New Civil Code (NCC) adopted in 2009. Also authors will examine in which way and why these regulations should be translated in the clinical pediatric practice. As a conclusion, pediatric clinicians should implement in their day-by-day practice these legal exigencies. We mean the medical full information and the informed consent to medical treatments need to be obtained from both parents, because parents assume both of them the responsibility for the life and health of the child.

Key Words: *Informed Consent / pediatrics / surrogacy / autonomy / legal issues*

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1. General considerations on Informed Consent

Informed Consent is an ethical concept that has become integral to contemporary medical practice. Informed Consent process supposes two movements: one, to provide information in order to obtain a positive feedback; second, to have the consent and the permission from the patient to perform treatments, surgery or other medical procedures. The Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization (WHO) define in 2002, the Informed Consent such as "a decision to participate in research, taken by a competent individual who has received the necessary information; who has adequately understood the information; and who, after considering the information, has arrived at a decision without having been subjected to coercion, undue influence or inducement, or

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intimidation" (Guideline 4: Individual informed consent). This is the general rule, for adults and competent, people who can understand the information, can ask more information, can accept or refuse treatments. But the pediatric practice is an exception from the general rule. Here patients are not competent, from legal point of view to accept or to refuse treatments and physicians need to provide all medical information to legal representative, who are, in the most of part of cases, the parents of the patients.

Providing information and obtaining informed consent in pediatric practice is a complex scenario for all involved: clinicians, parents, children, legal representatives, ethical counselors, psychologists. Parents have legal and moral authority to make decisions on behalf of their children, although that authority is not absolute and their decisions must be in the best interest of the child (Miller, 2006:177-178).

2. Forms of Informed Consent

The Informed Consent contains two major elements: comprehension and free consent. Comprehension is awareness and understanding about the patient's medical condition and possibilities. It implies that patient has been given adequate information about diagnosis, prognosis, alternative treatments choices, including the option of refusal of proposed treatment. This information should be provided in language that is understandable to the particular patient, who may have linguistic or cognitive limitation. Comprehension is necessary for there to be freedom in consenting (American College of Obstetricians and Gynecologists, 2004:10).

Free consent is an intentional and voluntary act that authorizes someone else to act in certain ways. This consent also includes *voluntariness*, which means the willingness of patient to undergo treatment; *capacity*, when the patient is able to understand nature of treatments; and *knowledge*, sufficient information as to nature of treatment disclosed to the patient (Barton, 1996: 38).

Kaushik, *et al*. (2010:1040) present different form of Informed Consent used in the medical practice, according to the following table.

Consent by Proxy or Surrogate Consent	Informed permission given by the parents or legal guardian as an authority and a responsibility to safeguard the welfare and best interest of their issue.
Informed Assent	Child's agreement to medical procedures in circumstances where he or she is not legally authorized or lacks sufficient understanding for giving consent competently.
Implied Consent	When the parents bring their child to a physician for treatment of any ailment it implies that they are agreeing for their child to go through the medical examination in the general sense.

Expressed Consent	When a patient specifically grants the physician permission to undertake the diagnosis and treatment of a specific problem. It may be an oral or a signature/written consent.
Valid informed consent	Consent with emphasis on patient's understanding ability of the reasonable and irrational elements of his/her decision.

3. Minors and the Informed Consent

The United Nations Convention on the Rights of the Child (New York, 1989) purports to reflect international convergence on the rights of children, on how decisions concerning children should be made, and on how children ought to be treated by the state and by their parents. This Convention recommends in art. 12 that "states parties shall assure to the child who is capable of forming his or her own views the right to express those views freely in all matters affecting the child, the views of the child being given due weight in accordance with the age and maturity of the child".

But under 4 years old, the child is very sensitive to any invasive intervention, because he/she cannot understand the purpose and all he/she knows is that he/she goes to a doctor, it hurts. After 4 years, progressively, the child begins to understand what is happening and begin to be curious to find out the cause and the evolution of its disease. After 7-8 years, the child can understand explanations increasingly more complex, physio-pathological mechanisms, even the necessity of some treatments. Sometimes, some children with chronic diseases become "matures", being able to understand and accept their disease, even better than adults. It was observed that the shift from non-decisional stage to the wish to participate in making a decision is made around the age of 9 years old. At 11, already is starting the relative affirmation of the autonomy and children expect to be asked, first, their consent. However, it cannot set an age to mark the moment when the children have some ability to discern, because it depends greatly from case to case (Buta, 2008: 60).

From legal point of view, minors are considered incompetent to make decisions. The medical treatment of children is authorized by parents, usually, or, in unusual circumstances, by other people who had received legal representative status. In practice, the principle of representation raises two main issues: first, sometimes it is necessary to establish the relevance of parents' preferences when they contradict doctors' recommendations. Secondly, children become able to express their preferences at different ages, from case to case, and when they express their own wishes, they should be taken into account and determine whether their preferences are relevant and substantiated (Benatar, 2008: 127-131).

In Romania, according to the NCC, art. 38, (1) and (2), the legal capacity is acquired at the age of majority, which este18: "the full legal capacity begins at the time when the person becomes major. The person becomes major at the age of 18". The full legal capacity refers to the ability of a person to be part into legal civil law acts, it is a law state, that is acquired only at a certain age and it is different from the capacity of discernment, which differ greatly from one child to another (Buta, 2008: 64).

Parent's responsibility is a matter of moral, social and legal order. The fact that parents are responsible for the good of their children is generally accepted. However, the discretion of the parents is not absolute. As children get grown-up to express their preferences and to motivate them, they are entitled to have rights and to be respected their preferences. However, it is sometimes difficult to assess how rational are their choices, because, often, children are not fully aware about consequences and therapeutic alternatives to treatments (Kenny, 200: 121-126).

To inform the sick and hospitalized child is a necessity and a pretty difficult thing. In the process of transmitting the medical information to a child should, it must to be taken into account some aspects (Buta, 2008: 58-59), such as:

- The new information disrupts the system of knowledge and representations that the child had created;
- The child should be seen as a whole (physical, psychological, social) and taking into account the culture, family and socio-economic background;
- When a child receives information, he/she should not be held solely as responsible, but there are other levels of responsibility, such as the family and the entourage, in order to avoid the child's tendency to self-blame. It is important that the clinician recognize, in front of the child, the difficulty to respect, exactly, his/her choices;
- The way of empowering the responsibility of the child is to develop his/her autonomy

Certain types of decisions that can be taken by minors are specified in the law. People, who are under the age of 18, can go to the doctor on their own initiative. But if their problem is not an emergency, they can be treated only with the consent of their parents or legal guardians. However, there are some exceptions to this rule (Miller, 2005: 21-29), such as:

- Drug abuse and sexually transmitted diseases (contraception, abortion). The most of part of states allow minors to make decisions on contraception and on treatment for drug addiction without parental consent.
- "Emancipated" minors are those who are living independently of parents, physically, financially or in any other way. In this category, of emancipated minors enter: married minors, those who are in the army,

and those who are living away from home at the college. These minors can ask for treatments without parental consent.

- "Mature" minors are those who are under the age of majority, but who have a rational thought. Such individuals are putting doctors in a dilemma: on the one hand, minors seem to be able to decide for themselves, legally, but on the other hand, parents are responsible and make decisions for them.

Authorities have agreed that physicians may respond to requests for such patients under the following conditions (Miller, 2005: 21-29):

(A) the patient is older than 15 years and seems to be able to understand the proceedings and risks,
(B) therapeutic measures are taken for the benefit of the patient (he/she is not an organ donor or a subject in research),
(C) measures can be justified as being necessary in from medical point of view and
(D) there is a good reason for which the parental consent cannot be obtained (including the minor's refusal to ask the parental consent).

It is also recommended for clinicians to clarify to the minor all details of invoices, because these invoices sent to parents may violate existing confidentiality in the doctor-patient relationship.

4. Legal aspects regarding guardianship of minors in Romanian law system

If the patient is minor, the informed consent will be done by parents. But the clinician should also inform the minor, if he or she is able to understand the information. Parents are the legal representative for their children, because it is presumed that they act for the best interest of the minor. (Aluas, 2016: 54). According to the Law 95/2006 on health reform (art. 650) the legal age to give the informed consent is 18. Minors could give the informed consent by themselves, without parents or legal representatives, only in these two cases:

a) Emergency, when parents or legal representatives cannot be contacted, and the minor is able to understand his or her medical;

b) Medical situations about the diagnosis and/or the treatment of sexual and reproductive conditions, at the express request of the minor who has more than 16 years old.

4.1. The exercise of parental authority jointly and equally

Parental authority can be defined as the ensemble of rights and powers that the law accords the father and the mother with respect to the person and the goods of their non-emancipated minor children, to the end of their accomplishing the

duties of protection, education, and support that are incumbent on them (Rubellin-Devichi, 1999:339).

According to the NCC, art. 483 (1) and (3), parents have the quality of co-holders of parental authority and both parents are responsible for raising their minor child. Art. 503 (1) of the NCC provides the fact that parents shall jointly and equally exercise parental rights (whatever their status is or whether they live together or not) and so fulfill their duties on their child's person and property.

Depending on the age and the maturity of the child, parents ought to associate all decisions relating to him/her [Art. 483 (2) NCC], allowing information and clarification of the child on all acts and deeds which could affect him/her and taking into account his/her opinion [art. 488 (2) b) NCC]. If parents are divorced, the joint parental authority is preserved (art. 397 NCC) and only if there are serious reasons the court can decide the exercise of the parental authority only by one of the parents, on the child's best interest [art. 398 (1) NCC] (Florian, 2011: 301).

According to the art.503 (2) NCC, if the third-party is in good faith and one of parents meets current single act for exercising rights and fulfilling parental duties, he/she is presumed to have the consent of the other parent. The law presumes the mutual tacit mandate between parents, for current acts when the third party is in *bona fide*, he/she did not have been aware of the lack of the consent of the other parent for the performance of the act (Florian, 2011: 302).

Interpreting this article, we can consider that a clinician, a physician, generally speaking, is a third party in *bona fide*, because the physician acts always for the good of patients. But in other countries, like France, according to the French courts, medical treatments and surgeries cannot be considered ordinary acts. Therefore, these acts presume the informed consent of each parent. Exceptions are only the routine treatments such as consultation and dental treatment, or other treatments for general prevention (mandatory vaccinations) and emergency treatments (Florian, 2011:302).

4.2. Exceptions

By derogation to the rule of joint custody, the court may decide that the authority be exercised by one of the parents in case of dissolution of marriage, nullity or annulment of marriage [art. 305 (2) and art. 505 (2) NCC] and in the case of children born out of wedlock, whose parents are not living together (Florian, 2011:303-304).

In each situation mentioned above, it is necessary the existence of serious reasons and the compliance of this measure with the best interests of the child [art. 398 (1) NCC]. Listening to the child aged over 10 years is mandatory and his/her opinion will be taken into account, according to the maturity of the child (art. 264 NCC).

If one of the parents is deceased, declared dead by the court order, under interdiction, deprived of the exercise of parental rights, or if, for any reason, is in the impossibility to express the will, the other parent carries the parental authority (art. 507 NCC). If both parents are in any of these situations, it will be establishing the guardianship of the child, by the court decision (art. 110 NCC).

4.3. Losing the exercise of the parental authority

Losing the exercise of parental rights is the sanction imposed to the parent who endangers the life, health or development of the child (art. 508 NCC). The measure is one of protecting the child, who will be protected against the risks to which he/she is exposed by the parent, either directly and concretely through child maltreatment, abusive behavior, negligence or default by addictions or habits (alcohol or drugs) incompatibles with the mission of growth and training of the child. Losing the exercise of parental rights is total, all rights are removed, those on the person of child, as well as on child's property and they are extended to all children born until the date of judgment. Only in certain situations, depending on the findings of the court, deprivation of parental rights may be partial, only on certain parental rights, or only to some of children, but only if this does not jeopardized growth, education, learning, development and training of children (art. 508-512 NCC).

If one parent has lost the parental rights, but the other holds the exercise of the parental authority, the latter one will take over all rights and duties relating to the person and rights of the child (art. 507 NCC) (Florian, 2011:307-308).

5. Ethical issues on in the pediatric practice

5.1. The principle of beneficence vs. the principle of autonomy

In the day-by-day medical practice the medical obligation to respect the principle of patient's autonomy is frequently in conflict with the principle of beneficence. The clinician wants to do what is the best for his/her patient, the minor, in our case, and the parents who are autonomous refuse to consent to the initiation of treatments or surgeries. The clinician must respect equally the principle of autonomy and the beneficence, but has no convenient solution for all those involved in the medical decision in such situations: children, parents, physicians, and legal authorities.

Another ethical issue is related to the information received by the patient in order to make an informed decision. Patient information must be complete and presented to the proper level of understanding of each patient. Also, the doctor has a duty to check that the provided information was properly understood by the patient. This is a big challenge for the health professional. Because there are between 12,000 and 15,000 specific terms of medicine, that only those with specific training understand them and use them correctly. This fact hinders the easy communication

between doctor and patient and could make difficult the patient fully understand of consequences of his/her decision and choices (Aluas, 2014: 15).

5.2. Obligation of the health professional to provide medical care could be in conflict with the duty to inform the patient

In the first chapter, art. 1 the Medical Deontology Code (2012), states that the main role of the physician is to ensure public health through disease prevention, investigation, diagnosis and implementation of all interventions needed to healing, in order to reintegrate the patient into society.

In the exercise of the medical profession, the physician should show availability, commitment, fairness and respect for his/her patients. The medical obligation to provide care to patient is qualified, traditionally, to be one of "prudence and diligence" because the physician has a duty to make every endeavor to get the patient healing. However, not achieving the desired result, the healing, it does not mean that the physician has failed to fulfill an obligation and cannot be a proof of his/her culpable conduct (Boila, 2009: 365).

But also the physician can be involved in some situation and he/she will be responsible for bad consequences or results of his/her medical decision.

Summarily, the main criteria of a medical culpable conduct are:

• Fraudulent, intentional fault, committed with the intention of producing harmful consequences;

• Professional misconduct due to the incompetence, ignorance, by violating the obligation to improve professional competence;

• Professional negligence or carelessness, by failing to take necessary precautions to avoid the risk of injury;

• Professional misconduct when the doctor acting carelessly, though aware of the potential risks;

• Guilt by omission when the doctor refuses to provide with medical care that are into his obligations;

• Fault for unauthorized practice;

• Fault on patient rights, to violation of the patient's confidentiality and medical secrecy, incorrect and incomplete information of the patient and his failure to obtain informed consent (Boila, 2009: 373).

Another professional duty of the doctor provided in the art. 649 of Law no. 95/2006 on Health Reform, is the obligation to inform the patient, in an accurate, complete and understandable way, on his/her medical condition, diagnosis, investigations that are necessary, prognosis and the risks that may arise from the application of certain treatments. Protecting patients involves also informing them about risks of performing a medical act, procedure (Viney, 2006: 27).

The obligation to inform the patient is a professional obligation and the purpose is the transparency of the medical decision, the need for loyalty, good

faith of the doctor, and the patient's right to make decisions concerning his/her life and health. The patient's decision to undergo the proposed medical act is largely influenced by data and information provided by his/her physician (Boila, 2009:384).

5.3. The best interest of the minor: who and about which criteria could assess it

The UN Convention on the rights of the child states in the art. 3 that „in all actions concerning children, whether undertaken by public or private social welfare institutions, courts of law, administrative authorities or legislative bodies, the best interests of the child shall be a primary consideration". The art.18 also mention this concept such as: "States Parties shall use their best efforts to ensure recognition of the principle that both parents have common responsibilities for the upbringing and development of the child. Parents or, as the case may be, legal guardians, have the primary responsibility for the upbringing and development of the child. The best interests of the child will be their basic concern". This is one of the most used expressions in the children's rights institution, but it is not explained in a clear words and criteria.

In the medical practice with minors as patients, sometimes we can face with problems regarding the person who will decide for the minor. Who is/are this/these person/s: parents, grandparents, tutors, authorities, clinicians, or pediatricians? The most important thing for a clinician is not only to identify the best person who acts in the best interest of the minor, but also to find the good solution when parents or legal representatives are in conflict regarding the treatments for the minor. Usually in this situation the clinician can ask a solution to the clinical ethics committee, an interdisciplinary committee, who will debate and will propose a recommendation. The clinician can take into account this recommendation or can decide in a different way, because the clinical recommendation is not mandatory for the physician. Generally, those who make the final decision need to be able to demonstrate that their purposes were, indeed, the best interest for that patient (Aluas, 2016:56).

6. Final Remarks

By adopting the New Civil Code in 2009 by the Law no. 287, Romania has new provisions regard to minors, to the joint guardianship: both parents must decide on their minor child, whether they are married or not, if they are separated, if divorced or living together with the child. These provisions are applicable in all areas, including medical ones, apart from the routine and treatments carried out urgently. In all pediatric units should be implemented protocols, good practices or guidelines that provide steps in informing and obtaining informed consent when

the minor patient come to the physician alone or only with a parent. A support for physicians could be the clinical ethics committees, charged with the examination of difficult cases and the recommendation on what should be done when the clinician is faced with difficult or even conflicting decisions.

We consider that this study has highlighted the relevance of the importance of this topic for Romanian medical and legal context. We have shown that even if legal regulations provide the joint guardianship of minors in all situations, in the medical practice these regulations need to be clarified and interpreted, in order to harmonize the medical practice with the law in force.

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